

TAZOCIN EF®

Piperacillin sodium/tazobactam sodium for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TAZOCIN EF. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking TAZOCIN EF against the benefits this medicine is expected to have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What TAZOCIN EF is used for

The name of your medicine is TAZOCIN EF. It contains the active ingredients piperacillin sodium and tazobactam sodium. They belong to a group of antibiotics called penicillins that work by killing bacteria.

Piperacillin is an antibiotic that kills many types of bacteria. Tazobactam belongs in the penicillin group but does not have activity against bacteria. It helps piperacillin to overcome bacteria which have become resistant to piperacillin.

TAZOCIN EF is active against bacteria which cause serious infections such as:-

- Chest infections
- Urine infections
- Stomach infections
- Skin infections
- Gynaecological infections
- Septicaemia (blood poisoning).

It is also used to treat many other infections. In hospitalised children aged 2 to 12 years, TAZOCIN EF is used to treat serious infections in the abdomen. TAZOCIN EF is not recommended to treat abdominal infections in children under 2 years.

TAZOCIN EF will not work against infections caused by viruses such as colds or flu.

This medicine is available only with a doctor's prescription.

TAZOCIN EF is not addictive.

Before you are given TAZOCIN EF

When you must not receive TAZOCIN EF

Do not have TAZOCIN EF if:

1. you have ever had an allergic reaction to:
 - piperacillin, tazobactam, or any other penicillin antibiotics
 - any antibiotic in the cephalosporin group
 - medicines called beta-lactamase inhibitors.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

2. TAZOCIN EF should not be given to children under two years of age unless directed by the child's doctor.

Before you start to receive TAZOCIN EF

You must tell your doctor if:

1. you are allergic to any foods, dyes, preservatives or any other medicines
 2. you have any other health problems, including kidney or liver disease
- The dose of TAZOCIN EF will be altered, depending on blood tests.
3. you are on a low salt diet
 4. you are pregnant or plan to become pregnant

Your doctor will discuss the risks and benefits of using TAZOCIN EF if you are pregnant.

5. you are breastfeeding

TAZOCIN EF passes into breast milk. Therefore, if you are breast-feeding, you should discuss with your doctor whether to stop breast-feeding while or stop using TAZOCIN EF.

6. you are being treated with TAZOCIN EF for gonorrhoea, your doctor should test you for syphilis as well.
- TAZOCIN EF in high doses may hide early symptoms of syphilis without curing it long-term.

If you are not sure whether you should be taking TAZOCIN EF, talk to your doctor.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

There may be interference between TAZOCIN EF and some other medicines, including:

- medicines for gout (probenecid)
- aminoglycoside antibiotics, including tobramycin
- vancomycin, an antibiotic
- preparations used for thinning blood (warfarin, heparin)
- methotrexate, used to treat cancer, rheumatoid arthritis and other inflammatory conditions
- vecuronium, a muscle relaxant used in surgery.

These medicines may be affected by TAZOCIN EF or may affect how well it works. You may need to be given different amounts of your medicine or you may need to be given different medicines.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking TAZOCIN EF.

How TAZOCIN EF will be given to you

How much you will be given

The dosage of TAZOCIN EF is generally 4.5g every eight hours. The dose may vary between 2.25g and 4.5 g and may also be given every six hours. For children aged 2 to 12 years, weighing up to 40 kg, and with normal kidney function, the recommended dosage is 112.5 mg/kg (100 mg

piperacillin/12.5 mg tazobactam) every 8 hours. For children aged 2 to 12 years, weighing over 40 kg, and with normal kidney function, the recommended dose is 4.5 g (4 g piperacillin/0.5 g tazobactam) every 8 hours.

Your doctor may change these dosages.

If you have kidney disease your doctor will adjust the dose to suit you.

How TAZOCIN EF will be given

A doctor or nurse in hospital will always give TAZOCIN EF to you. It will usually be given to you as a slow injection into a vein over 20-30 minutes.

How long you will receive TAZOCIN EF

The length of time you will be given TAZOCIN EF depends on the type and severity of your infection. It should be given for at least five days, and for 48 hours after all signs of illness and fever have gone.

Overdose

It is unlikely that you will ever receive an overdose of TAZOCIN EF because it will be given by a trained nurse or doctor.

While you are receiving TAZOCIN EF

If you receive TAZOCIN EF for a prolonged time, your doctor may wish to do some blood tests. Sometimes blood disorders can occur if you take TAZOCIN EF.

If a doctor asks you for a urine sample, tell him/her that you are receiving TAZOCIN EF.

Antibiotics in the penicillin family, including TAZOCIN EF, can cause interference in some tests for glucose in urine. Penicillins that are excreted in urine can cause a false-positive result. The doctor will request a test, which is not affected by penicillins.

Things you must do

If you develop severe diarrhoea, tell your doctor immediately. Do this even if it occurs several weeks after stopping TAZOCIN EF.

This may be a sign of a serious side effect that affects the bowel. You may need urgent medical care. Do not take any medicines to treat this diarrhoea without checking with your doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TAZOCIN EF.

TAZOCIN EF is effective in most people, but may have unwanted side effects in some. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. The more common side effects are:

- nausea or indigestion
- vomiting
- diarrhoea or constipation
- rash, itchy or red skin
- allergic reactions such as hives

- a new infection caused by bacteria that are resistant to TAZOCIN EF (superinfection)
- difficulty sleeping
- headache, dizziness or light-headedness

Rare side effects are:

- increased sweating
- eczema
- flaking or peeling of the skin
- inflammation of the mouth
- dry mouth
- weakness and tiredness
- hallucinations or severe confusion
- muscle or joint pain or prolonged muscle relaxation
- fever
- hot flushes
- swelling of the hands, feet and ankles
- swelling or redness along a vein which is extremely tender when touched
- changes in liver function including jaundice (yellowing of skin and eyes) or hepatitis
- severe diarrhoea caused by a certain superinfection in the gut
- convulsions ('fits') if TAZOCIN EF is given in high doses
- short-term changes in kidney function
- cough, fever, chills, shortness of breath and chest pain
- thrush, especially with prolonged treatment.

Less often, serious effects have occurred in people taking TAZOCIN EF.

Tell your doctor or nurse if you notice any of the following and they worry you:

- pain, swelling, or redness around the injection site
- skin rash
- itchiness.

Tell your doctor immediately if you notice any of the following:

- severe blisters and bleeding in the lips, eyes, mouth, nose or genitals
- itchy spots accompanied by fever and feeling unwell
- tiredness, being short of breath and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nose bleeds.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything on this list or anything else that is making you feel unwell.

Importantly, tell your doctor if you have severe diarrhoea in the next few weeks after TAZOCIN EF treatment.

Do not try to treat it yourself with medicines that you can buy without a prescription.

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using TAZOCIN EF

Storage

It is unlikely that you will be asked to store this medication. If you are:

Keep this medicine where young children cannot reach it.

A locked cupboard at least 1 and a half metres above the ground is a good place to store medicines.

Keep TAZOCIN EF in a cool, dry place where it stays below 30°C. Protect from light. Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking TAZOCIN EF, or it has passed its expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like and how it is supplied

TAZOCIN EF is a white powder, which is supplied 4.5 grams of powder in glass containers (vials).

The powder containing 4 g of piperacillin and 500 mg (0.5 g) of tazobactam is mixed with sterile liquid to give a solution for injection by your doctor.

Ingredients

TAZOCIN EF vials contain piperacillin sodium and tazobactam sodium as the active ingredients and also contain citric acid monohydrate and disodium edetate (EDTA).

Supplier

TAZOCIN EF is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW 2000

Toll Free Number: 1800 675 229

www.pfizer.com.au

Australian Registration Number:

TAZOCIN EF 4.5 g: AUST R 132525

Date of preparation

This leaflet was prepared in May 2019.

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